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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/549,096 | 04/12/00 | WARE | C 07246-030001 |

HM12/0830

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| EXAMINER | |
|---|---|
| HUYNH, P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | 8 |

**DATE MAILED:** 08/30/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/549,096 | WARE, CARL | |
| | Examiner | Art Unit | |
| | " Neon" Phuong Huynh | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-50* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *See Continuation Sheet* .

Continuation of 20. Other: Raw Sequence Listing Error report and Notice to comply.

## DETAILED ACTION

1. **Please note** the location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/or Amino Acid Sequence Disclosure.

   This application fails to comply with the sequence rules. Please see enclosed RAW SEQUENCE Listing Error Report and notice to comply.

3. Claims 1-50 are pending in instant application.

### *Election/Restrictions*

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-4, 7-16, drawn to isolated or recombinant homotrimeric p30 polypeptide, pharmaceutical composition, kit, classified in Class 424, subclass 184.1; Class 530, subclass 300.

   II. Claims 5-6, drawn to a fusion protein comprising a p30 polypeptide and tag, classified in Class 530, subclass 351.

   III. Claims 17-19, drawn to a pharmaceutical composition comprising an expression vector and kit, classified in Class 514, subclass 44.

   IV. Claims 20-21 and 23-25, drawn to a method of inducing proliferation in lymphocyte using anti-HVEM antibody, classified in Class 424, subclass 130.1.

   V. Claims 20 and 22-25, drawn to a method of inducing proliferation in lymphocyte using polypeptide, classified in Class 424, subclass 184.1.

   VI. Claims 20 and 22-25, drawn to a vector encoding a p30 polynucleotide or cell expressing a recombinant p30 as a cell associated p30 polypeptide, classified in Class 536, subclass 23.5 and Class 435, subclass 69.1.

VII. Claims 26-32 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated rheumatoid arthritis using a soluble polypeptide, classified in Class 424, subclass 184.1.

VIII. Claims 26-32 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated insulin-dependent mellitus using a soluble polypeptide, classified in Class 424, subclass 184.1.

IX. Claims 26-32 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated multiple sclerosis using a soluble polypeptide, classified in Class 424, subclass 184.1.

X. Claims 26-32 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated systemic lupus erythematosus using a soluble polypeptide, classified in Class 424, subclass 184.1.

XI. Claims 26-32 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated myasthenia gravis using a soluble polypeptide, classified in Class 424, subclass 184.1.

XII. Claims 26-30, and 33-36, drawn to a method of inhibiting a p30 polypeptide mediated cellular response involving a reaction to a transplant using a soluble polypeptide, classified in Class 424, subclass 184.1.

XIII. Claims 26-31 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated cellular response wherein the inhibited response modulates a T lymphoma using a soluble polypeptide, classified in Class 424, subclass 184.1.

XIV. Claims 26-31 and 34-36, drawn to a method of inhibiting a p30 polypeptide mediated cellular response wherein the inhibited response modulates a B lymphoma using a soluble polypeptide, classified in Class 424, subclass 184.1.

XV. Claims 26-32 and 37, drawn to a method of inhibiting a p30 polypeptide mediated rheumatoid arthritis using anti-p30 antibody, classified in Class 424, subclass 130.1.

XVI. Claims 26-32 and 37, drawn to a method of inhibiting a p30 polypeptide mediated insulin-dependent mellitus using anti-p30 antibody, classified in Class 424, subclass 130.1.

XVII. Claims 26-32 and 37, drawn to a method of inhibiting a p30 polypeptide mediated multiple sclerosis using anti-p30 antibody, classified in Class 424, subclass 130.1.

XVIII. Claims 26-32 and 37, drawn to a method of inhibiting a p30 polypeptide mediated systemic lupus erythematosus using anti-p30 antibody, classified in Class 424, subclass 130.1.

XIX. Claims 26-32 and 37, drawn to a method of inhibiting a p30 polypeptide mediated myasthenia gravis using anti-p30 antibody, classified in Class 424, subclass 130.1.

XX. Claims 26-31, and 37, drawn to a method of inhibiting a p30 polypeptide mediated cellular response wherein the inhibited response modulates a T lymphoma using anti-p30 antibody, classified in Class 424, subclass 130.1.

XXI. Claims 26-31, and 37, drawn to a method of inhibiting a p30 polypeptide mediated cellular response wherein the inhibited response modulates a B lymphoma using anti-p30 antibody, classified in Class 424, subclass 130.1.

XXII. Claim 38, drawn to a method of treating tumor using an expression vector, classified in Class 514, subclass 44.

XXIII. Claims 39-40 and 42-44, drawn to a method of modulating a lymphotoxin beta receptor mediated cellular response using polypeptide to inhibit herpes virus entry into cell, classified in Class 514, subclass 2.

XXIV. Claims 39, 41 and 42-44, drawn to a method of modulating a lymphotoxin beta receptor mediated cellular response using an anti-p30 antibody inhibit herpes virus entry into cell, classified in Class 424, subclass 130.1.

XXV. Claims 45-50, drawn to a method for inhibiting virus production in a cell using polypeptide, classified in Class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III, VI are different products. They differ with respect to their physiochemical properties, structures and mode of action. Therefore, they are patentably distinct.

Groups (I/V, VII-XIV, XXIII, XXV), (III, VI/XXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be practice with materially different process such as various methods of use in Groups V, VII-XIV, XXIII and XXV for p30 polypeptide, Group XXII for vector. Therefore, they are patentably distinct.

Inventions of Group II and Groups IV, XV-XXI and XXIV are unrelated products and methods and are therefore patentably distinct.

5. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

6. Due to the complexity of the claimed invention, an oral restriction was not made.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
Aug 27, 2001

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640

Application No.: 09/549,096

# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☑ 7. Other: Please see RAW Sequence Report. Alternatively, Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.

## Applicant Must Provide:

☑ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☑ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☑ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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